

REMARKS/ARGUMENTS

By the foregoing amendment, independent claim 53 has been amended and dependent claims 58, 60 and 61 have been cancelled. Entry of this amendment after final is proper because 1) the amendment places the application in condition for allowance, 2) the amendment raises no new issues that would require further searching and 3) the amendment lessens the number of claims and thereby lessens the number of issues that will be presented on appeal. Additionally, this amendment addresses items brought up in the final office action.

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Claim 53 has now been amended to specify that the imaging apparatus is on or in the catheter body and that the marker comprises an electronic marker circuitry associated with the imaging apparatus to form, on an image received from the imaging apparatus, an indication of the trajectory on which the trajectory on which the tissue penetrating element will advance while the tissue penetrating element is still in the first position. These limitations were within the scope of claim 53 prior to the amendment and merely serve to narrow and clarify the claimed subject matter. Support for these amendments is found throughout the specification including Paragraphs 0126-0127. No new matter has been added.

In the final Office Action, new grounds for rejection were raised, rejecting all claims 53-58 and 61-63 over United States Patent No. 5,464,395 (Faxon et al.) in combination with United States No. 5,749,848 (Jang et al.). In view of the fact that new grounds for rejection were raised, Applicant does not believe that it was proper or fair for the rejection to have been made final. Applicant reserves the right to file a petition under Rule 181 seeking withdrawal of the finality of the office action in the event that the present amendment is refused entry.

The final Office Action states at page 4 that Jang et al. inherently describes one or more imageable markers useable in conjunction with an imaging apparatus. Applicant disagrees. The law on inherency has been succinctly stated by the United States Court of Appeals, as follows:

To establish inherency, the *extrinsic evidence* must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient.

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added)

Stated another way, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) In *Levy* the Board considered a claim directed to a balloon catheter having a biaxially oriented balloon. The examiner had rejected that claim over a prior art patent that disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462. The examiner had argued that the prior art balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

In this case, the record contains no extrinsic evidence and no reasoning whatsoever to establish that Jang et al. must *necessarily* include the "maker and imager" as the Office Action contends. Thus, Applicant respectfully submits that inherency has not been established.

Irrespective of whether Jang et al. inherently discloses an imageable marker or not, the presently amended claims are patentably distinguishable over Faxon et al., Jang et al. and all

other prior art of record. No prior art of record describes or even remotely suggests a catheter system that has a tissue penetrator advanceable from a catheter body, a lumen extending through the tissue penetrator, a guidewire that is advanceable through the lumen of the tissue penetrator, an imaging apparatus on or in the catheter body and useable to image the target location; and electronic marker circuitry associated with the imaging apparatus to form, on an image received from the imaging apparatus, an indication of the trajectory on which the tissue penetrating element will advance, as recited in independent claim 53. Thus, the subject matter of independent claim 53 is allowable over all prior art of record. Dependent claims 54-57 and 62-63 further define the subject matter of claim 58 and are also allowable on at least the same grounds as claim 53 and possibly other grounds not specifically articulated here.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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